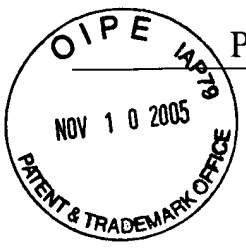

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TRANSMITTAL LETTER
APPEAL BRIEF

Applicant	:	Cohen et al.
App. No	:	09/989,684
Filed	:	November 20, 2001
For	:	APPARATUS AND METHODS FOR SEPARATING AGGLUTINANTS AND DISPERSE PARTICLES
Examiner	:	Samuel P. Siefke
Art Unit	:	1743

CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

November 7, 2005
(Date)

Russell M. Jeide, Reg. No. 54,198

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing in the above-identified application are the following enclosures:

(X) Appeal Brief in thirteen (13) pages.

The present application qualifies for Small Entity Status under 37 CFR 1.27.

FILING FEES:

FEE CALCULATION				
FEE TYPE		**FEE CODE**	**CALCULATION**	**TOTAL**
Appeal Brief	*41.20(b)(2)*	2402 ($250)		$250
			TOTAL FEE DUE	$250

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Docket No. : NAGACO.055A **Customer No.: 20,995**

Application No. : 09/989,684

Filing Date : November 20, 2001

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Dated: November 7, 2005

Russell M. Jeide
Registration No. 54,198
Attorney of Record
Customer No. 20,995
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Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the Notice of Appeal filed August 4, 2005, Applicant submits this Appeal Brief.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real parties in interest are the joint owners of this application, Nagaoka and Co. LTD, located at 4-7-18, Nishinomiyahama, Nishinomiya Hyogo, Japan, and Burstein Technologies, Inc., located at 23052 Alicia Pkwy, Suite H471, Mission Viejo, CA 92692

II. RELATED APPEALS AND INTERFERENCES

The Appellant knows of no other appeals or interferences which will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III.STATUS OF CLAIMS

Claims 9, 12, 15-31, 77-78 and 91-94 are pending prior to filing of this Appeal Brief. By this paper, Appellant requests that the Board cancel pending Claims 91-94. Alternatively, Appellant will cancel these claims upon remand to the Examiner. Appellant reserves the right to pursue the subject matter of Claims 91-94 in one or more continuing applications claiming priority to the instant application.

In view of the cancellation of Claims 91-94, Claims 9, 12, 15-31, 77-78 are the pending claims involved in this appeal and Claims 9, 77, and 78 are the pending independent claims involved in this appeal. Claims 12 and 15-31 depend from independent Claim 9.

Summary of Prosecution

The above-captioned application was filed on November 20, 2001 with Claims 1-90. The application, including the originally filed Claims 1-90, was published as U.S. Publication No. *Publication No. 2002/0196435* on December 26, 2002. In response to a Restriction Requirement mailed May 28, 2004, Appellant elected Claims 9-31, 77-79, and 81 for prosecution in the present application. An Amendment filed on December 21, 2004 cancelled Claims 10, 11, 13, 14, 79, and 81; amended Claims 9, 12, 15-19, 21-23, 25, 77, and 78; and added new Claims 91-

94. Thus, after entry of the December 21, 2004 Amendment, Claims 9, 12, 15-31, 77, 78, 80, and 91-94 were pending. These claims were each finally rejected in an Office Action dated May 4, 2005. On August 4, 2005, Appellants filed a Pre-Appeal Brief Request, along with a Pre-Appeal Brief and a Notice of Appeal. The Pre-Appeal Brief addressed reasons for patentability of each of the pending independent Claims, namely, Claims 9, 77, 78, and 91, and their respective dependent claims. On October 7, 2005, a Notice of Panel Decision from Pre-Appeal Brief Review was mailed, indicating Claims 9, 12, 15-31, 77-78 and 91-94 remained rejected and noting that the time period for filing an appeal brief will be reset to be one month from mailing of the decision, i.e., November 7, 2005.

IV. STATUS OF AMENDMENTS

No amendments were made in response to the Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present application includes three independent claims that are involved in this appeal. The claimed subject matter is discussed below, with citations to corresponding portions of the specification and drawings as required by 37 C.F.R. § 41.37(c)(1)(v). These citations are provided in order to illustrate specific examples and embodiments of the recited claim language, and not to limit the claims.

The claims of the present application are generally directed towards systems and methods of separating particles in a sample and quantifying the separated portions of particles. The pending claims each refer to an optical disc having a separation structure configured to separate particle agglutinants from disperse particles. As those of skill in the art will recognize, particles of interest in a biological compound may be agglutinated by the addition of one or more proper reagents having an affinity for the particles of interests, where the remaining particles are not agglutinated by addition of the reagent. As recited in the pending claims, the particle

agglutinants may then be separated from the remaining disperse particles. As explained in paragraph 9 of the present application (U.S. Publication No. *2002/0196435*):

> A biological sample material is dispensed into the entry chamber. An assay reagent including particles bound with at least one type of bioactive agent is dispensed into the entry chamber. The biological sample material is mixed with the assay reagent. The biological sample material is allowed to react with the assay reagent to thereby facilitate formation of an agglutinant. The optical disc is rotated so that non-agglutinated particles escape from the entry chamber through the separation zone structure. Where the agglutinated particles remain, the disc is made to allow an interrogating light beam to be reflected from or transmitted past the particles to allow detection, imaging, and/or counting of the particles.

As noted above, one aspect of the present application is related to counting an amount of particle agglutinants and/or disperse particles on an optical biodisk. Figure 9 of the present application, reproduced below, illustrates "microfluidic circuit 612A of FIG. 8 having agglutinated particles 1202 and disperse particles 1204, and inner and outer sets 1206, 1208 of tracks used for quantitating the agglutinant and disperse particles." *Publication No. 2002/0196435*, paragraph [0067]. Appellant notes that the definition of "quantitate," as recited in the *The American Heritage® Dictionary of the English Language is* "[t]o determine or measure the quantity of." *The American Heritage® Dictionary of the English Language, Fourth Edition,* Copyright © 2000 by Houghton Mifflin Company.

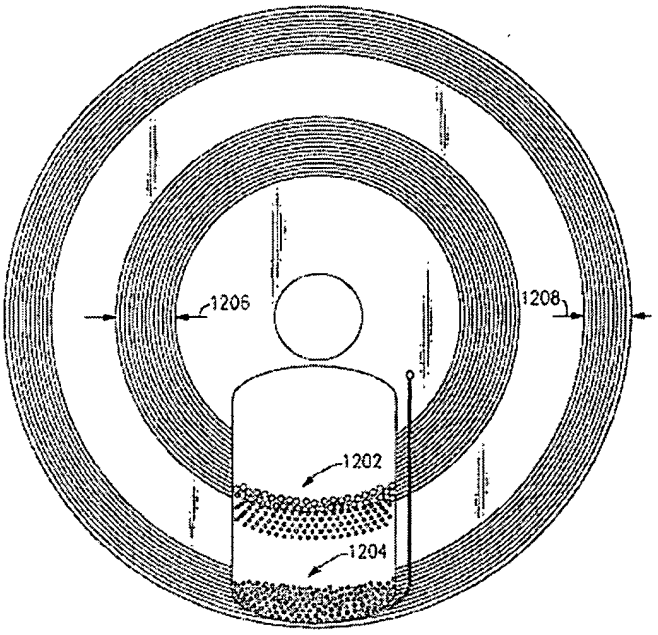


FIG.9

The present appliation further teaches that "quantitating the agglutinant or the disperse particles is achieved by *counting the number of tracks* in the entry chamber or the collection zone, respectively, which are covered by the material being quantitated. A method for determining the volume of agglutinant or disperse particles includes *counting the number of tracks* related to the known volumetric size of the respective microfluidic chamber." *Id.*, paragraph [0121] (emphasis added). Accordingly, the present application teaches quantification of disperse and/or particle agglutinants through a process of separating the disperse particles from the particle agglutinants and then counting the number of tracks of an optical biodisc that are covered with the respective particles, e.g., disperse particles or particle agglutinants. Thus, in one embodiment, "[t]he optical disc is rotated so that non-agglutinated particles escape from the entry chamber through the separation zone structure [and a] *quantity* of disperse particles or particle agglutinants is determined by *counting the number of optical disc tracks* in the collection zone or entry chamber, respectively, that are covered by the disperse particles or particle agglutinants." *Id*, paragraph [0122] (emphasis added).

Another aspect of the present application is the use of separation structures for separating disperse particles and particle agglutinates.

> In an aspect of the invention, an optical disc or rotating apparatus has a separation zone structure having solid components spaced apart to form gaps. The gaps are large enough to allow disperse particles to change position relative to the center of rotation by passing through the separation zone structure. The gaps are too small to allow particle agglutinants to pass through the separation zone structure." *Id.*, paragraph [0007].

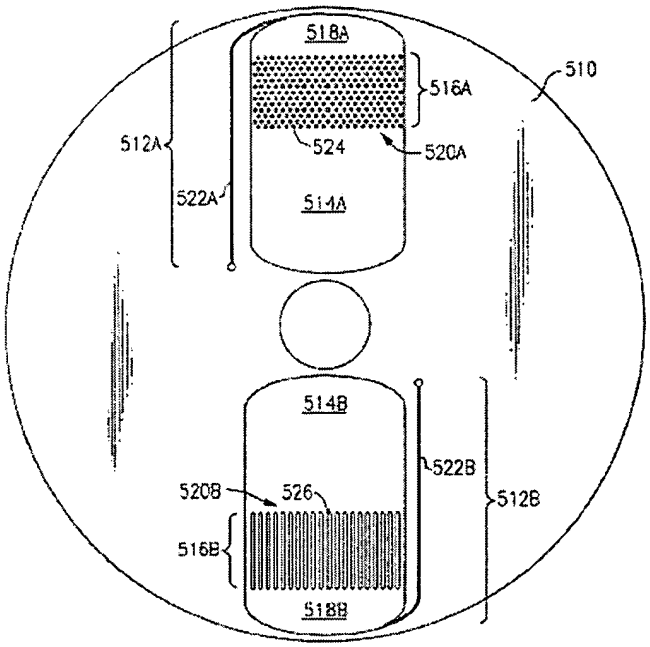


FIG.5

Figure 5 of the present application, reproduced above,

> ...illustrates an optical bio-disc 510 including two embodiments of microfluidic circuits 512A, 512B for separation and quantitation of agglutinated microparticles or cells. Each microfluidic circuit, when filled with an agglutination assay reaction, separates agglutinants from disperse material. Each circuit is implemented on a rotatable platform whereby centrifugal acceleration provides a force applied to move the particles throughout the circuit. ... The circuits have respective agglutinant entry chambers 514A, 514B, each of which is of sufficient

> size to accommodate the entire sample volume ... After the entire volume of the agglutination reaction is loaded into the entry chamber, the platform is spun for time t_1. Disperse particles (e.g., non-agglutinated particles or particles having less than a particular level of agglutination) or cells pass through a respective separation zone 516A or 516B into a respective collection zone 518A or 518B. Agglutinated cells or particles collect at the respective entry area 520A or 520B of the separation zone and can subsequently be quantitated. ... [T]he separation zone includes a field of obstructions (e.g., posts such as post 524) having spacing that is smaller than that of the smallest anticipated agglutinant (i.e., the spaces between the posts or obstructions are narrower than the width of the smallest anticipated agglutinant). In circuit 512B, the separation zone includes a field of bars (e.g., ribs such as rib 526) having spacing that is smaller than that of the smallest anticipated agglutinant." *Id.*, paragraphs [0051] to [0053].

As described above, the separation structures of the present application are sized to allow disperse particles to pass through, while retaining particle agglutinates.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following rejections are to be reviewed on appeal:

1. Whether Claims 9, 12, 25-31, 77, and 78 are properly rejected under 35 U.S.C. § 102(e) as being anticipated by Virtanen (U.S. Patent No. 6,030,581).

2. Whether Claims 15-24 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Virtanen (U.S. Patent No. 6,030,581).

VII. ARGUMENT

Prior to discussion of the three above-listed grounds of rejection to be reviewed on appeal, Appellant includes a brief overview of the prior art reference cited in both the 102(e) and 103(a) rejections listed above.

Virtanen describes, in general:

> [An] optical disk, adapted to be read by an optical reader, comprising a first sector having substantially self-contained assay means for localizing an analyte suspected of being in a sample to at least one, predetermined location in the first

> sector and a second sector containing control means for conducting the assay and analyte location information, with respect to one or more analytes suspected of being in a sample, accessible to the reader, wherein the presence or absence of the analyte at said location is determinable by the reader using the control means and the location information. *Virtanen,* Abstract.

In Virtanen, an "analyte binds to a predetermined location on the disk if it is present in the sample, and the presence of the analyte is detected by the reader from information that identifies the particular analyte with the location at which it is bound." *Id.* at col. 5, ll. 44-48. Thus, Virtanen appears to determine if a particular analyte is present in a sample by detecting, using various means, whether any analyte binds to respective locations of the optical disk, where the location information indicates at which respective location each of the analytes of interest will bind, if present in the sample.

Following are remarks regarding each of the grounds of rejection listed above in Section VI. For at least the reasons described below, the rejections of Claims 9, 12, 25-31, and 77-78 are improper and should be reversed.

1. Claims 9, 12, 25-31, and 77-78 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Virtanen (U.S. Patent No. 6,030,581).

Discussion of Disperse Particle Quantification

Claim 77 recites, in pertinent part:

> An optical disc for separating disperse particles from particle agglutinants, comprising: a plurality of tracks disposed on an outer periphery of the optical disc ... wherein a quantity of disperse particles may be determined by using the light detector to count a number of the plurality of tracks that are covered by the disperse particles.

Thus, the apparatus of Claim 77 determines an approximate quantity of disperse particles contained in a sample by counting a number of tracks on the outer periphery of the optical disc

that are at least partially covered by disperse particles that have passed through the separation structure.

Applicant respectfully submits that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. See M.P.E.P. § 2131. On page 4 of the May 4, 2005 Final Office Action, the Examiner states, "[w]ith respect to quantifying the agglutinants in the entry chamber by determining an amount of the tracking groove that is at least partly covered by particle agglutinants, Virtanen discloses the analytes bind to a predetermined location on the disk if it is present in the sample and the presence of the analyte is detected by the reader from information that identifies the particular analyte with the location at which it is bound (col.5, lines 44-47)." The portion of Virtanen cited by the Examiner recites: "[t]he analyte binds to a predetermined location on the disk if it is present in the sample, and the presence of the analyte is detected by the reader from information that identifies the particular analyte with the location at which it is bound." *Virtanen*, col. 5, lines 44-47. Thus, while Virtanen may detect the presence of a particular analyte based upon its location on the optical disc, Virtanen does not teach or suggest quantitating of particles and, more particularly, Virtanen does not teach or suggest that "a *quantity* of disperse particles may be determined," as recited in Claim 77. Furthermore, Virtanen does not teach or suggest quantitating disperse particles using a detector "to *count a number of the plurality of tracks that are covered by the disperse particles*," as recited in Claim 77. Because Virtanen fails to expressly or inherently describe each and every element of Claim 77, Virtanen does not anticipate Claim 77.

Independent Claims 9 and 78 each include systems or methods for quantitating that are similar to those recited in Claim 77. For example, Claim 9 recites, "[a]n optical disc comprising a tracking groove positioned at least partly beneath the entry chamber and proximate the separation structure, wherein particle agglutinants in the entry chamber can be *quantified by determining an amount of the tracking groove that is at least partly covered by particle agglutinants*," and Claim 78 recites that "a *quantity of particle agglutinates* may be determined

by using the light detector to *count a number of the plurality of tracks* that are covered by the particle agglutinates." Thus, Applicant respectfully asserts that Virtanen fails to teach or suggest at least the above-quoted elements of Claims 9 and 78 for the same reasons as discussed above with respect to Claim 77. Reconsideration of Claims 9, 77 and 78, and their pending dependent claims, is respectfully requested.

2. Claims 15-24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Virtanen (U.S. Patent No. 6,030,581). As noted above, Claims 15-24 depend from Claim 9 and are, therefore, believed to be allowed for the same reasons discussed above with respect to Claim 9, as well as their own patentable features.

VIII. CLAIMS APPENDIX

9. An optical disc comprising:

a microfluidic circuit that is responsive to centrifugal force resulting from rotation of the disc, the circuit comprising:

an entry chamber positioned proximate a center of the optical disc and configured to hold a specimen having disperse particles and particle agglutinants;

a collection zone positioned proximate an outer edge of the optical disc;

a separation structure positioned between the entry chamber and the collection zone, the separation structure comprising a plurality of structures that define gaps therebetween, the distance between the gaps being less than or equal to the width of the particle agglutinants, the separation structure being configured to separate particle agglutinants from the disperse particles when the specimen is urged toward the separation structure by centrifugal force created when the optical disc is rotated; and

a tracking groove positioned at least partly beneath the entry chamber and proximate the separation structure, wherein particle agglutinants in the entry chamber can be quantified by determining an amount of the tracking groove that is at least partly covered by particle agglutinants.

12. The optical disc of claim 9, further comprising a collection tracking groove positioned in the collection zone, wherein the presence of the disperse particles in the collection zone can be determined by coverage of the collection tracking groove by disperse particles.

15. The optical disc of claim 9, wherein the separation ~~zone~~ structure includes a series of slits formed in the optical disc, each slit having a predetermined width that allows disperse particles to pass therethrough while causing particle agglutinants to be retained in the entry chamber.

16. The optical disc of claim 15, wherein the slits are formed by a series of rib structures.

17. The optical disc of claim 16, wherein the series of rib structures are substantially parallel to each another.

18. The optical disc of claim 16, wherein the series of rib structures are radially directed from the center of the disc.

19. The optical disc of claim 10, wherein the predetermined width of each slit decreases as a function of increasing distance from the center of the disc.

20. The optical disc of claim 18, wherein each of the rib structures has a width that increases as a function of increasing distance from the center of the disc.

21. The optical disc of claim 9, wherein each of the structures comprises a post having a predetermined diameter.

22. The optical disc of claim 21, wherein a diameter of consecutive posts increases as a function of increasing distance from the center of the disc.

23. The optical disc of claim 21, wherein the number of posts per unit area increases as a function of increasing distance from the center of the disc.

24. The optical disc of claim 15, wherein the width of the slits decreases as a function of increasing distance from the center of the disc.

25. The optical disc of claim 9, wherein the structures comprise a filter having a preselected porosity so that when the optical disc is rotated, disperse particles escape from the entry chamber and particle agglutinants are retained in the entry chamber.

26. The optical disc of claim 25, wherein the filter is formed from a material selected from the group consisting of glass fiber and plastic fiber.

27. The optical disc of claim 26, wherein the glass fiber is formed from a material selected from the group consisting of alumina, silica, and quartz.

28. The optical disc of claim 26, wherein the plastic fiber is formed from a material selected from the group consisting of cellulose acetate, cellulose nitrite, mixed cellulose esters, polyethersulfone polyvinyl chloride, polycrylonitrile, polycarbonate, polysulfone, polyfluorotetra-ethylene, polyvinylidene-fluoride, and cellulose.

29. The optical disc of claim 25, wherein the filter is formed from a material selected from the group consisting of glass particles and plastic particles.

30. The optical disc of claim 29, wherein the glass particles are formed from a material selected from the group consisting of alumina, silica, and quartz.

31. The optical disc of claim 29, wherein the plastic particles are formed from a material selected from the group consisting of cellulose acetate, cellulose nitrite, mixed cellulose esters, polyethersulfone polyvinyl chloride, polycrylonitrile, polycarbonate, polysulfone, polyfluorotetra-ethylene, polyvinylidene-fluoride, and cellulose.

77. An optical disc for separating disperse particles from particle agglutinants, comprising:

a plurality of tracks disposed on an outer periphery of the optical disc;

a main chamber disposed between at least a portion of the plurality of tracks and a light detector, the main chamber comprising:

an entry chamber configured to accept a sample; and

a separation structure comprising solid components spaced apart to form gaps, the gaps being large enough to allow disperse particles to change position relative to the center of the disc by passing through the separation structure, the gaps being too small to allow particle agglutinants to pass through the separation structure;

wherein a quantity of disperse particles may be determined by using the light detector to count a number of the plurality of tracks that are covered by the disperse particles.

78. An optical disc for separating disperse particles from particle agglutinants, comprising:

a plurality of tracks disposed proximate a central portion of the optical disc;

a main chamber disposed between at least a portion of the plurality of tracks and a light detector, the main chamber comprising:

an entry chamber configured to accept a biological sample and an assay reagent, wherein the biological sample and the assay reagent are mixed to form particle agglutinates and disperse particles;

a collection zone configured to contain disperse particles; and

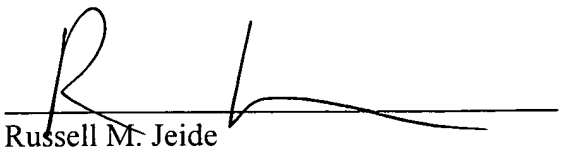
a separation structure having solid components spaced apart to form gaps, the gaps being sized so that particle agglutinates are retained in the entry chamber while disperse particles are allowed to pass through the separation structure into the collection zone when the optical disc is rotated, wherein a quantity of particle agglutinates may be determined by using the light detector to count a number of the plurality of tracks that are covered by the particle agglutinates.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.



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